

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korf et al 6013029 in view of Patsalos et al 5607390, Bergveld et al 6463312 and Pfeiffer 5640954. Korf in figure 2 shows a dialysis probe including an inlet portion 15 receiving dialysis fluid, a supply portion 13 coupled to the inlet portion for conducting dialysis fluid through the skin, a discharge tube 14 for conducting dialysis fluid out of the body, where the discharge fluid can be positioned perpendicular to the skin surface, 15, an outlet portion 27 coupled to the discharge tube at a joint portion 3 and 7, which joins the element 16 to element 27. The joint portion includes a sensor 3. It does not have the supporting plate. However, Patsalos et al teaches that in dialysis probes, it is desirable to have the access portion attached to a support plate 7, in order to prevent the needle from breaking loose inside the body (see column 1, lines 28-38). Hence it would have been obvious to modify Korf to use such a plate, to increase patient safety. In addition, Korf does not describe the structure of the tubes 13 and 14, the combination does not have the supply and discharge tubes connected and they are not membranes. However, Bergveld et al teaches an alternate access device which is a U-shaped membrane for the same purpose as the interface of Korf. Hence, it would have been obvious to use the access structure of Bergveld, as it is merely the selection of an element that is well known for the purposes of Korf. In addition, the combination does

not have the valve. Pfeiffer shows the same type of device as Korf et al, where there is a check valve 90 for preventing flow of fluid from the sensor back to the needle. Since the valve is before the sensor, it would be in the discharge tube. Hence, it would have been obvious to modify Korf et al to include such a valve, so as to control the fluid flow and maintain accurate readings. With respect to claim 31, the sensor is removable in that it can be taken out of the device.

Applicant's arguments filed 9/26/2007 have been fully considered but they are not found to be persuasive.

Applicant has asserted that Korf teaches against providing a check valve in that the purpose of Korf is to provide minimal flow rates that allow little or no power to be used. Using the valve, according to applicant would require power and hence contradict this goal of Korf. The examiner disagrees, noting first that a one way valve could be a mechanical valve and require no power. Secondly, it is the examiner's position that the minimal power increase necessitated by the valve would be outweighed by the gain in safety gained from using the valve to prevent backflow of fluids.

Applicant has asserted that Pfeiffer does not have the sensor adjacent the valve. This argument is not considered to be relevant to prosecution, as the question is whether the combination has the feature. As the examiner noted above, in the combination, the valve would be adjacent the sensor.

Applicant has challenged the examiner's position that adding the fluid valve would make the readings more accurate. The examiner notes that inherently,

preventing the backflow of fluid containing glucose to mix again with the new fluid would alter the readings and cause other safety concerns.

Applicant has asserted that impermissible hindsight has been used to piece the rejections together. The examiner disagrees, noting that there is motivation for each combination, particularly in view of the language in the KSR decision handed down by the Supreme Court.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

RLN
December 5, 2007

